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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,500	09/09/1999	RONALD TAYLOR	9426-019	1294

20583 7590 07/16/2002

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EXAMINER
CANELLA, KAREN A

ART UNIT	PAPER NUMBER
1642	18

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/392,500	Taylor et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *20-34, 48-53, 55, 56, and 58-62* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *48-53, 55, 56, and 58-62* is/are allowed.

6) ☒ Claim(s) *20-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

2. Claims 20, 21, 29, 30, 48, 49 and 50 have been amended. Claims 62 has been added. Claims 20-34, 48-53, 55, 56 and 58-62 are pending and under consideration.

3. The rejection of claims 58-61 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's arguments.

4. The rejection of claims 48-53, 55 and 56 under 35 U.S.C. 103(a) as being unpatentable over Kinders et al (US 6,221,621) in view of Perlman et al (Journal of Experimental Medicine, 1981, Vol. 153, pp. 1592-1603) and Michael et al (FASEB, 1993, Vol. 7, p A375 is withdrawn in light of applicants arguments.

5. The rejection of claims 20-34 under 35 U.S.C. 103(a) as being unpatentable over Kinders et al (US 6,221,621) in view of Perlman et al (Journal of Experimental Medicine, 1981, Vol. 153, pp. 1592-1603) and Michael et al (FASEB, 1993, Vol. 7, p A375 is maintained for reasons of record. In response to applicant's argument that the claimed subject matter as a while would not have been obvious to one of skill in the art at the time the invention was made, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant argues that Kinders does not teach the detection of cancer in an animal by administering to said animal a labeled antibody which specifically binds to C3b(i). However, it was not stated that Kinders administered an antibody to

C3b(i) but that Kinders taught the nexus between the presence of the C3 protein and the presence of a cancer (column 7, lines 29-34). Kinders further taught the detection of C3 and C3b in the urine of cancer patients by an anti-C3 monoclonal antibody. Michael teaches that C3b(i) is expressed by malignant epithelium. Pearlman et al teach that the C3b(i) fragment constituted the largest C3 fragment that was deposited on target cells (page 1595, lines 6-7). Michael et al teach the expression of C3b(i) by malignant epithelium. Thus it would be obvious given the combined teachings of Kinders and Pearlman and Michael that C3b(i) represented an in vivo tumor cell target. Thus it would be obvious to substitute an anti-C3b(i) antibody for the anti-C3 antibody of Kinders for the detection of cancer in vivo. response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
July 15, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

L3 ANSWER 5 OF 6 BIOSIS COPYRIGHT 2002 BIOLOGICAL ABSTRACTS INC.
ACCESSION NUMBER: 1993:246786 BIOSIS
DOCUMENT NUMBER: PREV199344119986
TITLE: Synthesis of iC3b/C3d and expression of a CD21-like protein
by malignant epithelium.
AUTHOR(S): Michael, E. J.; Hostetter, M. K.
CORPORATE SOURCE: Univ. Minn., Minneapolis, MN 55455 USA
SOURCE: FASEB Journal, (1993) Vol. 7, No. 3-4, pp. **A375**.
Meeting Info.: Meeting of the Federation of American Societies for Experimental Biology on Experimental Biology '93 New Orleans, Louisiana, USA **March 28-April 1, 1993**
ISSN: 0892-6638.
DOCUMENT TYPE: Conference
LANGUAGE: English

L1 ANSWER 1 OF 1 MEDLINE
ACCESSION NUMBER: 81241375 MEDLINE
DOCUMENT NUMBER: 81241375 PubMed ID: 7252421
TITLE: Interaction of target cell-bound C3bi and C3d with human lymphocyte receptors. Enhancement of antibody-mediated cellular cytotoxicity.
AUTHOR: Perlmann H; Perlmann P; Schreiber R D; Muller-Eberhard H J
CONTRACT NUMBER: AI 07007 (NIAID)
CA 27489 (NCI)
HL 07195 (NHLBI)
SOURCE: JOURNAL OF EXPERIMENTAL MEDICINE, **(1981 Jun 1) 153** (6) **1592-603.**
Journal code: 2985109R. ISSN: 0022-1007.
PUB. COUNTRY: United States
Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 198109
ENTRY DATE: Entered STN: 19900316
Last Updated on STN: 19970203
Entered Medline: 19810925

AB The occurrence and distribution of distinct receptors for three C3 fragments on purified human blood lymphocytes were studied by rosette formation. Indicator cells were bovine, chicken, or sheep erythrocytes (E) bearing up to 100,000 molecules of human C3b (EC3b) without antibody. EC3b was converted to C3bi-bearing-E (EC3bi) with purified C3b inactivator (factor I) and beta1H (factor H), and to C3d-bearing E (EC3d) by treatment of EC3bi with trypsin. Using bovine E (Eb) as indicators, approximately 11% of the lymphocytes bound EbC3b, 6% bound EbC3bi and 2% bound EbC3d. Fractionation of the lymphocytes by adsorption to monolayers of C3-fragment-bearing Eb or by rosetting indicated that most of the cells with receptors for C3b were distinct from those having receptors for C3bi and/or C3d. Cells from two lymphoblastoid cell lines (Raji and Daudi) formed strong rosettes with EC3b, which were weak. 51Cr-labeled E was used as a target in antibody, C3-fragment-bearing E was not lysed by the lymphocytes. However, at suboptimal concentrations of IgG enhancing capacity of the fragments occurred in the order of C3bi greater than C3d greater than C3b. In addition, C3-fragment-bearing cells inhibited the lysis of antibody-coated cells not concluded that target cell bound C3 fragments enhance ADCC by improving contact between target cells and those effector cells which have C3 receptors. Cell-bound C3 effector cells. It is proposed that certain lymphocytes are capable of interacting with C3bi in addition to C3b and C3d and that C3bi and C3d have a greater regulatory effect on their cytolytic function than C3b.